Florida DEP Draft Technical Support Document:

Derivation of Human Health-Based Criteria and Risk Impact Statement

February 2014

Imagine the result

ARCADIS

Background

- 1994
  - Florida Per Capita Fish and Shellfish Consumption Study suggested that Floridians eat significantly more fish than the standard rate assumed by USEPA
  - FDEP petitioned to consider using higher fish consumption rate for human health-based criteria
- 1998-2003
  - Baseline Risk Analysis conducted by University of Florida, submitted for comment and peer review
  - Incorporates a probabilistic approach
- 2008
  - Final Baseline Risk Analysis submitted to FDEP
- 2012
  - July: FDEP releases draft TSD, based on 2008 Baseline Risk Analysis
  - May, July-August: Public workshops leading to refinements to FDEP's approach
  - August-October: Human Health Peer Review Committee (HHPRC) recommendations lead to additional refinements
- 2013
  - March: FDEP releases revised draft TSD
  - April: FDEP presented proposed criteria to the Environmental Regulation Commission (ERC); ERC asked FDEP to develop RSCs and use the NCI methodology to derive fish consumption rates
- 2014
  - February: Current draft TSD released

Overview of February 2014 TSD

Probabilistic Approach

- Probabilistic approach was used to develop proposed criteria
- Characterize risk to Florida's entire population
- Several exposure pathways included
  - Fish consumption
  - Drinking water consumption
  - Dermal exposure while swimming (4 chemicals)
- Distributions used for many but not all parameters that determine potential exposure and risk

Distributions Used for Several Input Parameters

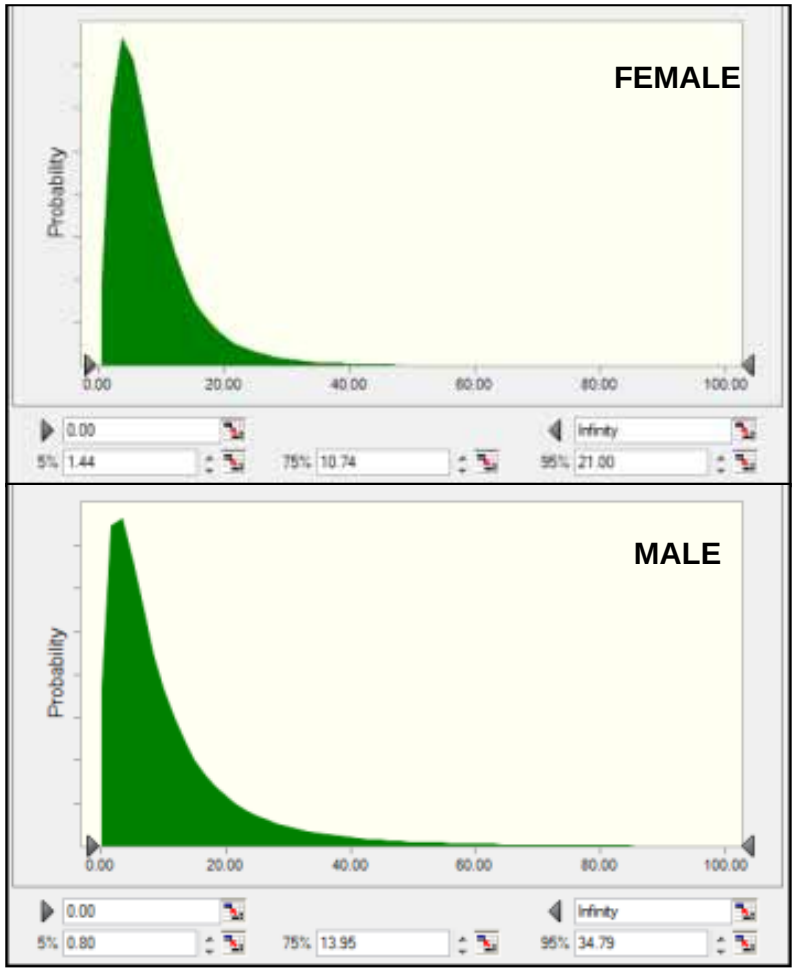
Distributions	Source
Male and female body weight (kg)	National
Sex (M/F)	Florida
Drinking water intake (mL/day)	National
Lipid (%)	Florida
Swimming frequency (events/year)	Florida
Swim time (hours/event)	National
Skin surface area (cm^2)	Calculated from body weight
Male and female fish consumption rate (g/day)	National
Point Estimates	**Source**
Reference dose (mg/kg-day)	Chemical-specific
Cancer slope factor $(mg/kg\text{-}day)^{-1}$	Chemical-specific
Relative source contribution (unitless)	Chemical-specific
Bioconcentration factor (L/kg)	Chemical-specific
Dermal absorption factors (units vary)	Chemical-specific

Fish Consumption Rates

- Based on 2003-2006 national NHANES data
  - Process for extracting regional NHANES data is still under development
  - Males and females age 19+
- National Cancer Institute (NCI) statistical methodology used to derive long-term daily consumption rates from short-term survey data
- Conversion factor of 1.5 used to convert NHANES cooked weight consumption rates to uncooked weight consumption rates

Fish Consumption Rates (cont.)

- Consumption rates adjusted to reflect only freshwater and estuarine species
  - Used proportion of freshwater and estuarine fish consumed, as reported in 1994 CSFII survey
- Some shrimp excluded from freshwater and estuarine consumption rate for compounds with BCFs less than 300
  - Shrimp caught beyond the 3-mile limit (44.5% of reported shrimp consumption) re-apportioned from estuarine to marine habitat
  - Compounds with BCFs less than 300 will readily depurate in the time it takes shrimp to migrate 3 miles offshore, therefore
  - No appreciable risk to human health

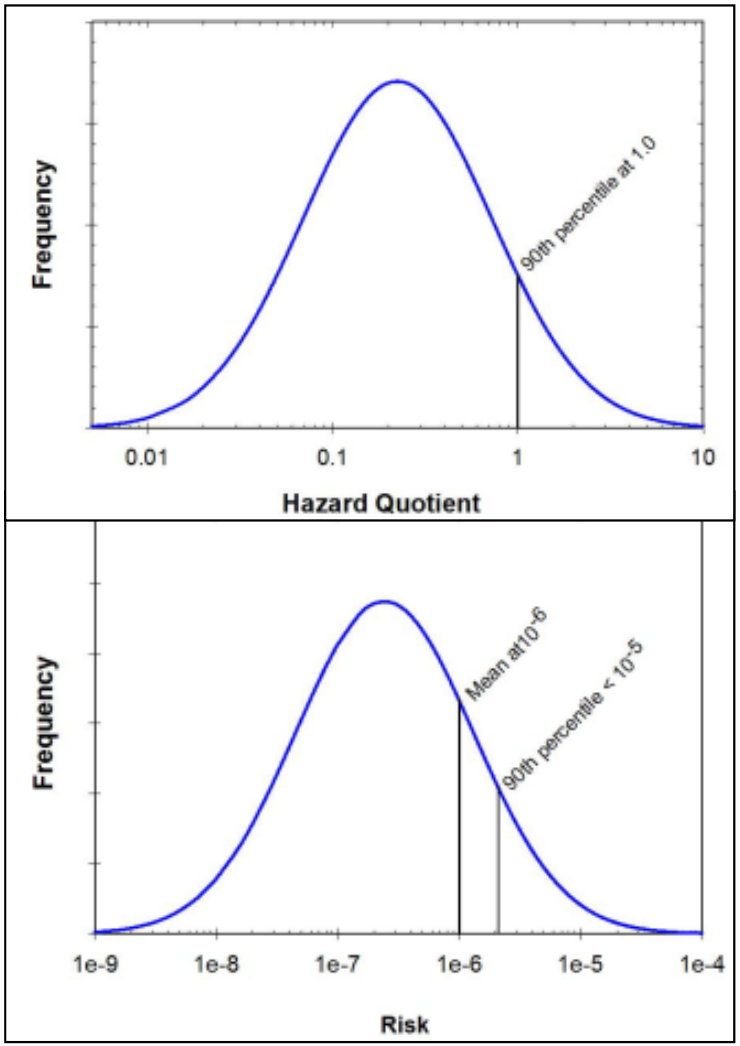


Relative Source Contribution

- RSCs describe the percentage of exposure to a given chemical that can be attributed to ambient water and fish consumption
- FDEP reviewed the literature and developed RSCs for 21 compounds with non-carcinogenic effects
  - RSCs range from 0.2 to 1.0
  - RSCs exceeding the 0.8 ceiling recommended by USEPA are recommended due to the robustness of the data and weight of evidence

Allowable Risk Benchmarks

- "The focus of criteria development should not be selection of a fish consumption rate or any other point value, but rather on setting criteria at the concentration of a pollutant in water that is not expected to pose a significant risk to human health over a lifetime."
- Criteria developed to protect Floridians at specified risk levels:
  - Hazard quotient of $\leq$1.0 at 90th percentile
  - Cancer risk of $\leq 10^{-6}$ at arithmetic mean;
  - Cancer risk of $\leq 10^{-5}$ at 90th percentile; and
  - Cancer risk of $\leq 10^{-4}$ at 95th and 99th percentiles



Development of Criteria

- Total of 68 criteria revised
- Ingestion of water and fish evaluated for all criteria
- Dermal exposure to water while swimming evaluated for 4 chemicals with assumed substantial dermal absorption
  - hexachlorobutadine, vinyl chloride, dichloromethane, N-nitrosodimethylamine
- Monte-Carlo simulations (with 100,000 iterations) used to characterize distributions of potential risk
- Subsequent to derivation, all carcinogenic criteria were evaluated using USEPA subsistence consumption rate (142.4 g/day) to verify that high consumers would be protected at 10^{-4} level

Current Status

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- RSC derivation submitted to USEPA February 3
- Entire TSD and additional RSC information provided to USEPA on February 14
- FDEP Seeking USEPA comment/concurrence before proposing revised approach and criteria to ERC
- USEPA readying release of national AWQC TSD
  - Scheduled for mid-April
- FDEP expects USEPA comments after release of national TSD
  - FDEP hope is USEPA will approve FDEP TSD even though may differ in some aspects from national approach

Contact Information

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Questions